

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL No.1456
LITIGATION)
) Master File No. 01-CV-12257-PBS
) Subcategory No. 06-CV-11337-PBS
)
) Judge Patti B. Saris
)
) Magistrate Judge Marianne B. Bowler
THIS DOCUMENT RELATES TO:)
United States of America ex rel. Ven-A-Care of)
the Florida Keys, Inc., et al. v. Boehringer)
Ingelheim Corporation, et al.,)
Civil Action No. 07-10248-PBS)

**THE ROXANE DEFENDANTS' MEMORANDUM IN SUPPORT OF
MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION
UNDER THE PUBLIC DISCLOSURE BAR OF THE FALSE CLAIMS ACT**

Helen E. Witt, P.C.
Anne M. Sidrys, P.C.
Eric T. Gortner
John W. Reale
KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, IL 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200

*Counsel for Defendants
Boehringer Ingelheim Corp.,
Boehringer Ingelheim Pharmaceuticals, Inc.,
Boehringer Ingelheim Roxane, Inc., and
Roxane Laboratories, Inc.*

Dated: June 26, 2009

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
PROCEDURAL BACKGROUND.....	1
I. THE COURT LACKS JURISDICTION OVER VAC'S CLAIMS BECAUSE THEY ARE BASED ON PUBLICLY DISCLOSED INFORMATION, AND VAC IS NOT AN ORIGINAL SOURCE.	3
A. The Allegations In The Complaint Were “Publicly Disclosed.”	4
1. The Relevant Allegations Are the Core Allegations in the Government’s 2008 Complaint (“Complaint”).....	5
2. WAC and AWP Inflation Was Publicly Disclosed Before Being Raised by VAC.	6
3. Allegations of “Inflated” Prices for Each Roxane Drug at Issue Were Publicly Disclosed Before Being Raised by VAC.....	9
4. The “Marketing the Spread” Allegations Were Publicly Disclosed Before Being Raised by VAC.....	12
B. VAC’s Action Is “Based Upon” The Publicly Disclosed Information.....	14
C. VAC Is Not An “Original Source” Of These Allegations.....	14
1. VAC’s Allegations Are Based Entirely on Second-Hand Data Compiled by and Acquired from Third-Party Sources.....	16
2. VAC Does Not Have Direct and Independent Knowledge of “Marketing the Spread” Allegations.....	19
CONCLUSION.....	20

TABLE OF AUTHORITIES

	<u>Page(s)</u>
Cases	
<i>A-1 Ambulance Serv., Inc. v. Cal.</i> , 202 F.3d 1238 (9th Cir. 2000)	5
<i>Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.</i> , 186 F. Supp. 2d 458 (S.D.N.Y. 2002).....	19
<i>In re Natural Gas Royalties Qui Tam Litig.</i> , 562 F.3d 1032 (10th Cir. 2009)	8, 9
<i>In re Pharm. Indus. AWP Litig.</i> , 491 F. Supp. 2d 20 (D. Mass. 2007)	11
<i>Kennard v. Comstock Res., Inc.</i> , 363 F.3d 1039 (10th Cir. 2004)	15
<i>Lee v. ABC Carpet & Home</i> , 236 F.R.D. 193 (S.D.N.Y. 2006)	15
<i>MacKenzie v. Kindred Hosp. E., LLC</i> , 276 F. Supp. 2d 1211 (M.D. Fla. 2003).....	4
<i>Rockwell Int'l Corp. v. United States</i> , 549 U.S. 457 (2007).....	4, 5, 15
<i>United States ex rel. Aflatooni v. Kitsap Physicians Serv.</i> , 163 F.3d 516 (9th Cir. 1999)	18
<i>United States ex rel. Atkinson v. Pa. Shipbuilding Co.</i> , 255 F. Supp. 2d 351 (E.D. Pa. 2002)	4, 5
<i>United States ex rel. Bannon v. Edgewater Med. Ctr.</i> , 406 F. Supp. 2d 907 (N.D. Ill. 2005)	5
<i>United States ex rel. Barth v. Ridgedale Elec., Inc.</i> , 44 F.3d 699 (8th Cir. 1995)	15
<i>United States ex rel. Feingold v. AdminaStar Fed., Inc.</i> , 324 F. 3d 492 (7th Cir. 2003)	5
<i>United States ex rel. Findley v. FPC-Boron Employees' Club</i> , 105 F.3d 675 (D.C. Cir. 1997).....	15

<i>United States ex rel. Hafter v. Spectrum Emergency Care, Inc.,</i> 190 F.3d 1156 (10th Cir. 1999)	15, 18
<i>United States ex rel. Haight v. Catholic Healthcare W.,</i> 445 F.3d 1147 (9th Cir. 2006)	5
<i>United States ex rel. Harshman v. Alcan Elec. and Eng'g,</i> 197 F.3d 1014 (9th Cir. 1999)	10
<i>United States ex rel. O'Keeffe v. Sverdup Corp.,</i> 131 F. Supp. 2d 87 (D. Mass. 2001)	15, 18
<i>United States ex rel. Precision Co. v. Koch Indus.,</i> 971 F.2d 548 (10th Cir. 1992)	4, 14
<i>United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.,</i> 384 F.3d 168 (5th Cir. 2004)	5
<i>United States ex rel. Rost v. Pfizer, Inc.,</i> 507 F.3d 720 (1st Cir. 2007).....	3, 4
<i>United States ex rel. Siller v. Becton Dickinson & Co.,</i> 21 F.3d at 1339 (4th Cir. 1994)	12
<i>United States ex rel. Smith v. Yale Univ.,</i> 415 F. Supp. 2d 58 (D. Conn. 2006).....	4
<i>United States ex rel. West v. Ortho-McNeil Pharm., Inc.,</i> 538 F. Supp. 2d 367 (D. Mass. 2008).....	3, 4, 5, 12, 13, 14, 15
<i>Vt. Agency of Natural Res. v. United States ex rel. Stevens,</i> 529 U.S. 765 (2000).....	15
<i>Wang v. FMC Corp.,</i> 975 F.2d 1412 (9th Cir. 1992)	14

Statutes

1 U.S.C. § 1	15
31 U.S.C. § 3730(b)(1)	15
31 U.S.C. § 3730(e)(4).....	4
31 U.S.C. § 3730(e)(4)(A)	3, 5, 14
31 U.S.C. § 3730(e)(4)(B)	15
42 U.S.C. § 1396r-8(k)(1)(A).....	9

Rules

Fed. R. Civ. P. 12(b)(1).....	4
Fed. R. Civ. P. 12(h)(3).....	4

Regulations

56 Fed. Reg. 7049-02 (1991)	9
-----------------------------------	---

INTRODUCTION

Relator Ven-A-Care’s (“VAC”) claims should be dismissed for lack of jurisdiction because it cannot show—as it must—that its allegations were not publicly disclosed before it filed its initial April 2000 complaint, or that it possesses the direct and independent knowledge necessary under the False Claims Act (“FCA”). *Years* before VAC filed its complaint, the record was replete with widespread public disclosures of purported AWP inflation and marketing the so-called “spread”. Particularly in the 1990s, VAC’s core claims against Roxane were repeatedly disclosed by multiple sources, including the Office of the Inspector General (“OIG”), the General Accounting Office (“GAO”), elected officials, the news media and in litigation.

Moreover, VAC cannot establish that it is an “original source” of this information. Indeed, VAC has **no** first-hand knowledge of Roxane’s alleged pricing and marketing practices. Rather, VAC concedes that all it has done is compile pricing data that was routinely disseminated by third parties to *thousands* of pharmacies across the country. Such widely accessible information cannot give rise to the “direct and independent” knowledge required of an “original source”. VAC also concedes that it has **no** relevant knowledge to support its “marketing the spread” allegations. Accordingly, VAC’s claims lack jurisdictional foundation, and this Court lacks jurisdiction over this case unless and until VAC’s claims are dismissed.

PROCEDURAL BACKGROUND

VAC filed its first complaint on April 10, 2000, alleging that Roxane made “fraudulent representations about the wholesale prices” of its drug Ipratropium Bromide (“Ipratropium”), allegedly causing harm to certain states’ Medicaid programs (*i.e.*, those that used WAC as a basis

for reimbursement). (Roxane Dkt. No. 2, Ex. 2 ¶¶ 86-88.)¹ Notably, the 2000 Complaint did not contain *any* allegations with respect to Roxane's published AWPs. Nor did the complaint assert any claims on behalf of the Medicare program, or contend that Roxane "marketed the spread."

On February 1, 2002, VAC filed a second amended complaint² ("2002 Complaint"), which added only Medicare claims and claims based on alleged AWP inflation for Ipratropium. (Roxane Dkt. No. 2, Ex. 4 ¶¶ 4, 173-78.) On February 15, 2005, VAC filed a third amended complaint ("2005 Complaint"), which alleged in a cursory fashion, for the first time, that "Defendants . . . [which collectively included *all* sealed defendants, not just Roxane] marketed the inflated Spread," but did not include any specific allegations against Roxane. (Roxane Dkt. No. 2, Ex. 5 ¶ 132.b.) VAC also named fifty-six drugs in addition to Ipratropium. Until the Government intervened in 2007, there were no specific allegations that Roxane marketed the spread. And Plaintiffs still have not identified any specific instances in which Roxane allegedly marketed the spread for a drug to any particular provider.

On January 18, 2007, the United States intervened in part of VAC's *qui tam* action, which, by then, had been pending for almost seven years. The Government asserted claims as to only nine of the drugs previously named by VAC: Ipratropium, Azathioprine, Diclofenac Sodium, Furosemide, Hydromorphone, Oramorph SR, Roxanol, Roxicodone, and Sodium Polystyrene Sulfonate. (Roxane Dkt. No. 1, Exs. A, B.) The Government brought claims on behalf of both the Medicaid and Medicare programs. (*Id.* ¶ 11.)

¹ Citations in this Motion refer to the docket for Case No. 07-10248-MEL ("Roxane Dkt."), to the extent the referenced pleadings appear on that docket, but not on the docket for Case No. 06-11337-PBS. Otherwise, citations to pleadings in this Motion refer to the docket for Case No. 06-11337-PBS ("Dkt.").

² In the interim, VAC filed a first amended complaint, without any substantive modifications or additions. (Roxane Dkt. No. 2, Ex. 3.)

Unlike VAC’s prior complaints, the Government’s 2007 Complaint also contained specific allegations pertaining to Roxane’s purported misconduct and marketing of the spread. For instance, the 2007 Complaint alleges that, prior to launching Ipratropium, Roxane “developed a pricing strategy designed to create an attractive spread between the AWP and the actual price” to “entice providers to purchase” that product. (*Id.* ¶ 61.) Moreover, the complaint includes targeted allegations that Roxane “falsely increase[d] the AWPs on [its] Furosemide products [in the year 2000] for the express purpose of creating a spread that would gain the company increased market share.” (*Id.* ¶ 63.) The complaint further alleges that Roxane “trained its sales force” on the “importance of the ‘spread’” and “actively marketed the spread” to “induce customers to purchase Roxane drugs.” (*Id.* ¶ 65.) VAC adopted the Government’s 2007 Complaint, *in toto*, dropping all claims in which the Government declined to intervene.³

I. THE COURT LACKS JURISDICTION OVER VAC’S CLAIMS BECAUSE THEY ARE BASED ON PUBLICLY DISCLOSED INFORMATION, AND VAC IS NOT AN ORIGINAL SOURCE.

Title 31 U.S.C. § 3730(e)(4)(A) provides that no court shall have jurisdiction over a *qui tam*, FCA action based on a “public disclosure,” unless the *qui tam* plaintiff is an “original source.” This jurisdictional bar prevents “parasitic relators” from bringing claims based on information already in the public domain, of which the relator has no first-hand knowledge. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007); *United States ex rel. West v. Ortho-McNeil Pharm., Inc.*, 538 F. Supp. 2d 367, 376 (D. Mass. 2008). Even when the Government has already intervened, a parasitic relator must be dismissed before the court can

³ The Government has since filed an amended complaint (“Complaint”) that is identical to the 2007 Complaint, except for the addition of three NDCs relating to the Novaplus ipratropium bromide product. (Dkt. No. 96.) VAC, again, adopted the Complaint *in toto*.

acquire jurisdiction to proceed. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 477 (2007). The party invoking jurisdiction under the FCA must allege in its pleading facts essential to show jurisdiction and must support those facts by competent proof. *United States ex rel. Precision Co. v. Koch Indus.*, 971 F.2d 548, 551 (10th Cir. 1992); *see Ortho-McNeil*, 538 F. Supp. 2d at 375. The court lacks subject matter jurisdiction and must dismiss the relator's action if: (1) there has been a "public disclosure," (2) the relator's suit is "based upon" the disclosure, and (3) the relator is not an "original source" of the information on which the suit is based. *Rockwell*, 549 U.S. at 470-71, 473-74.

The defense of lack of subject matter jurisdiction may be raised at any time by motion of a party or by the court *sua sponte*. Fed. R. Civ. P. 12(h)(3); *see MacKenzie v. Kindred Hosp. E., LLC*, 276 F. Supp. 2d 1211, 1218 (M.D. Fla. 2003). Analytically, Rule 12(h)(3) motions are identical to Rule 12(b)(1) motions; the only difference is that the former may be asserted at any time and need not be responsive to any pleading of the other party. *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 68 (D. Conn. 2006). In the context of a factual jurisdictional challenge—for example, when a defendant contests a relator's ability to satisfy the requirements of § 3730(e)(4)—the court is required to weigh and consider evidence outside the pleadings to determine whether subject matter jurisdiction exists. *Id.* at 69; *see Ortho-McNeil*, 538 F. Supp. at 375. Moreover, no presumptive truthfulness attaches to the relator's allegations, and the existence of disputed material facts does not preclude the trial court from evaluating for itself the merits of the jurisdictional claims. *United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 255 F. Supp. 2d 351, 362 n.9 (E.D. Pa. 2002).

A. The Allegations In The Complaint Were "Publicly Disclosed."

The FCA's jurisdictional bar applies when there is "some act of disclosure" of the alleged fraud "to the public outside of the government." *Rost*, 507 F.3d at 728. The disclosure need not

be widespread. *Ortho-McNeil*, 538 F. Supp. 2d at 376-77. Neither must it “contain an explicit ‘allegation’ of fraud,” *A-1 Ambulance Serv., Inc. v. Cal.*, 202 F.3d 1238, 1243 (9th Cir. 2000), as long as “the critical elements exposing the transaction as fraudulent are placed in the public domain,” *United States ex rel. Feingold v. AdminaStar Fed., Inc.*, 324 F. 3d 492, 496 (7th Cir. 2003). This Court, like many others, has adopted the following “X + Y = Z” analytical framework: allegations of fraud are publicly disclosed when “X”, the allegedly false state of facts, and “Y”, the facts set forth in the claims at issue, are revealed in some combination, such that readers or listeners may infer “Z”, that fraud has been committed. *Ortho-McNeil*, 538 F. Supp. 2d at 383-85. The disclosure need not actually identify the defendant—especially when it is not difficult to identify the potential wrongdoer—as long as it “set[s] the government squarely on the trail of fraud.” *Id.* at 383 n.10. Allegations may be publicly disclosed by any one of the various methods enumerated in the statute, including through government reports, audits, hearings, or news media reports. *See* 31 U.S.C. § 3730(e)(4)(A). The “elements of the fraud allegation need not be made public in a single document,” *United States ex rel. Haight v. Catholic Healthcare W.*, 445 F.3d 1147, 1151 n.1 (9th Cir. 2006), but rather can come from multiple sources “considered as a whole.” *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 174 n.8 (5th Cir. 2004).

1. *The Relevant Allegations Are the Core Allegations in the Government’s 2008 Complaint (“Complaint”).*

The relevant allegations here are those in the Government’s 2008 Complaint, not VAC’s initial or amended complaints. *See Rockwell*, 549 U.S. at 473, 474. Moreover, the time period for determining whether a public disclosure has occurred for a particular claim runs up to the date on which VAC raised that claim for the first time. *Atkinson*, 255 F. Supp. 2d at 367 n.15; *United States ex rel. Bannon v. Edgewater Med. Ctr.*, 406 F. Supp. 2d 907, 924 (N.D. Ill. 2005).

The Complaint asserts two theories of alleged fraud: *first*, that Roxane reported “inflated” WACs and AWPs for nine of its drugs; and *second*, that Roxane marketed the spread on those drugs. The following chart sets forth each of the core claims at issue, and the date those claims were first raised by VAC:

Public Disclosure Date	Core Claim(s) Raised By VAC
April 10, 2000	Roxane inflated the WACs for Ipratropium, causing Medicaid to over-reimburse for that drug. (Roxane Dkt. No. 2, Ex. 2 ¶¶ 86-88.)
February 1, 2002	Roxane inflated the AWPs for Ipratropium, causing Medicaid and Medicare to over-reimburse for that drug. (Roxane Dkt. No. 2, Ex. 4 ¶ 173-78.)
February 15, 2005 ⁴	Roxane inflated and marketed the spread on the WACs and AWPs for all nine drugs at issue. (Roxane Dkt. No. 2, Ex. 5 ¶¶ 131, 132.b.)

2. *WAC and AWP Inflation Was Publicly Disclosed Before Being Raised by VAC.*

Before VAC asserted its WAC-based claims in 2000, and *certainly* before VAC asserted its AWP-based claims in 2002, allegations of price inflation by the pharmaceutical industry as a whole, and particularly by generic manufacturers (like Roxane), had reached the public domain and sufficed to apprise the Government of Roxane’s alleged fraud.

Government Reports. In the 1980s and 1990s, the OIG studied the actual acquisition costs of prescription drugs at length and issued numerous, public reports concluding that published prices exceeded acquisition costs by substantial margins, causing Medicaid and Medicare to overpay for drugs:

⁴ Roxane contends that the specific marketing the spread allegations in this case first emerged in the 2007 Complaint, when the Government alleged that Roxane used specific schemes to create, manipulate, control, and market the spreads for its drugs. (Roxane Dkt. No. 1 ¶¶ 64, 65.) For purpose of the public disclosure analysis, however, this Motion applies a conservative, February 15, 2005 cut-off date for the marketing the spread allegations, in the event the Court were to find that such allegations were first raised in the 2005 Complaint.

- In 1989, the OIG issued a report alerting the Health Care Financing Administration (“HCFA”) that AWP was not a meaningful or reliable figure, and specifically recommending that HCFA *not* use AWP as a basis for payment in the Medicare program. (56.1 ¶ 11, Tab 82 (Sept. 1989 OIG Report) at 1, 7.)⁵
- In 1996, the OIG conducted a focused study on three nebulizer products (similar to Ipratropium) and concluded that HCFA overpaid for these drugs by \$11.7 million in 1994, due to its continued reliance on AWP. (*Id.* ¶ 80, Tab 127 (Feb. 1996 OIG Report) at 6.)
- In 1997, the OIG disclosed to HCFA (and the public) its nationwide estimate that the *average* discounts off AWP were 42.5%, which translates into an *average* spread of **73.9%** under Plaintiffs’ methodology. (*Id.* ¶ 21, Tab 89 (Aug. 1997 OIG Report) at 4.) The OIG also disclosed that “AWP” was commonly referred to as “Ain’t What’s Paid” (*id.* at 2), and identified manufacturers as the source of AWPs (*id.* at 1).
- In 1997, the OIG reported that for the generic drugs with the highest Medicare utilization, the spreads were as high as *900 percent*. (*Id.* ¶ 35, Tab 97 (Dec. 1997 OIG Report) at 8.) The OIG further disclosed to HCFA (and the public) that Medicare was making “excessive payments” for prescription drugs because of “significantly inflated AWP statistics,” which bore “little or no resemblance to actual wholesale prices.” (*Id.* at 9, 10.)

Media Reports. Elected officials at the highest levels of government also disclosed allegations of AWP inflation. Notably, in a 1997 radio address, President Clinton disclosed that AWP inflation was an industry-wide phenomenon that contributed to abuse in the Medicare system. In President Clinton’s words:

[O]ur Medicare program has been systematically overpaying doctors and clinics for prescription drugs . . . Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price – the so-called sticker price – for drugs. Few doctors however, actually pay the full sticker price. *In fact, some pay just one tenth of the published price* [which equates to a 1000% “mega spread”].

⁵ For the convenience of the Court, and to avoid filing multiple copies of the same document, this Motion cites to The Roxane Defendants’ Local Rule 56.1 Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment (“56.1”), to the extent evidence cited in the 56.1 also supports the arguments in this Motion.

(*Id.* ¶ 40, Tab 98 (12/13/97 Clinton Radio Address) at 1-2 (emphasis added).) Moreover, in 1999, Congressman Pete Stark publicly denounced the use of AWP, describing it as a “phony . . . system,” a “joke on the taxpayer,” and an acronym for “Ain’t What’s Paid.” (*Id.* ¶ 47, Tab 104 (9/2/99 Stark Press Release) at 1.)

The foregoing government and media reports about alleged industry-wide price inflation constitute a fraction of the public disclosures about VAC’s “critical allegation” that Roxane inflated the WACs and AWPs for its drugs.⁶ Because Roxane manufactures generic drugs, the Government could have easily drawn a connection between Roxane and the pricing inflation that was allegedly industry-wide. *See In re Natural Gas Royalties Qui Tam Litig.*, 562 F.3d 1032, 1042-43 (10th Cir. 2009).

Natural Gas illustrates this point in a factual context analogous to this case. In *Natural Gas*, the relator brought suit against more than 300 defendants, alleging that they used certain techniques to underpay the federal government for natural gas. *Id.* at 1037-38. The improper techniques had already been disclosed in Senate Committee documents alleging mismeasurement

⁶ For a non-exhaustive listing of additional public disclosures, *see* 56.1 ¶ 1, Tab 71 (June 1984 OIG Report); ¶ 2, Tab 72 (6/2/87 Test. of M. Zimmerman, Hr’g before H. Comm. on Ways and Means, Subcomm. on Health); ¶ 4, Tab 74 (2/12/89 *Phila. Inquirer*, “When Drugstores Tell You No”); ¶ 5, Tab 75 (2/24/89 *Newsday*, “No Rx for Plans; Drug Plans Draw Pharmacists’ Ire”); ¶ 6, Tab 76 (3/23/89 *Ark. Democrat-Gazette*, “Pharmacists Face Big Losses Under Proposal, Official Says”); ¶ 7, Tab 77 (4/4/89 *Wash. Post*, “Prescription Drug Plans Face Threat; Pharmacy Chains Dropping Programs”); ¶ 8, Tab 78 (5/1/89 *Drug Store News*, “AWPs Are a Joke, But No One Is Laughing”); ¶ 9, Tab 79 (7/18/89 Hr’g before S. Comm. on Aging, “Skyrocketing Prescription Drug Prices: Are We Getting Our Money’s Worth?”); ¶ 10, Tab 81 (Aug. 1989 Report of S. Comm. on Aging, “Prescription Drug Prices: Are We Getting Our Money’s Worth?”); ¶ 17, Tab 86 (6/11/90 *Drug Store News*, “There’s Nothing ‘Average’ About AWP”); ¶ 19, Tab 87 (Mar. 1993 GAO Report); ¶ 20, Tab 88 (Jan. 1994 GAO Report); ¶ 23, Tab 90 (11/7/1994 *Drug Topics*, “HCFA Taking Hard Look at Drug Costs”); ¶ 27, Tab 91 (Jan. 1996 Congressional Budget Office Report); ¶ 28, Tab 92 (2/27/96 Statement of Rep. P. Stark before H.R.); ¶ 29, Tab 94 (May 1996 OIG Report); ¶ 33, Tab 96 (1/2/97 *Wash. Post*, “Battling the High Prices Medicare Pays for Drugs”); ¶ 34 (June 1997 Report of H. Comm. on Budget); ¶ 45, Tab 102 (May 1998 OIG Report); ¶ 46, Tab 103 (1999 Department of Health and Human Services Report); ¶ 49, Tab 109 (5/10/00 *USA Today*, “House Committee Asks Drug Firms to Justify Pricing Policy”); ¶ 54, Tab 114 (Jan. 2001 OIG Report); ¶ 58, Tab 115 (5/7/00 *N.Y. Times*, “New Questions on Drug Plans as Costs Soar”); ¶ 61, Tab 117 (8/6/00 *N.Y. Times*, “Administration Plans Cuts in Some Drug Payments”); ¶ 65 (Sept. 2001 Hr’g Before H. Subcomm. on Health and H. Subcomm. on Oversight and Investigations).

of oil and gas on a large scale, and in other disclosures that named specific defendants, but indicated that the practice was industry-wide. *Id.* at 1039. According to the Tenth Circuit, the industry-wide disclosures triggered the public disclosure bar because they “provided specific details about the fraudulent scheme and the types of actors involved in it.” *Id.* at 1042. Consequently, the Government was in a position to target “specific actors and a specific type of fraudulent conduct.” *Id.* Moreover, the Government’s knowledge of, and contracts with, the parties paying for the natural gas, and the Government’s access to records related to the transactions enhanced its ability to investigate the fraud. *Id.*

Similarly to *Natural Gas*, the public disclosures here discussed a particular, industry-wide practice, namely, creating a “spread” between published AWPs and actual acquisition cost. *See id.* at 1039. Moreover, each manufacturer (including Roxane) must enter into a Rebate Agreement with HCFA, in order for its drugs to be covered under Medicaid, *see* 56 Fed. Reg. 7049-02 (1991), and must report to HCFA the “average manufacturer price” (“AMP”) for its drugs, *see* 42 U.S.C. § 1396r-8(k)(1)(A). Thus, by reference to its own records, the Government could have easily drawn a connection between Roxane and the allegedly industry-wide pricing inflation.

3. *Allegations of “Inflated” Prices for Each Roxane Drug at Issue Were Publicly Disclosed Before Being Raised by VAC.*

Ipratropium. VAC’s claims that Roxane created so-called “mega spreads” for Ipratropium were already publicly disclosed before VAC filed its 2000 Complaint alleging just WAC fraud, and *certainly* before 2002, when VAC first added its AWP claims. For instance, back in 1998, the OIG disclosed to HCFA, and the public, average spreads of 155% on Ipratropium. (56.1 ¶ 83, Tab 129 (Nov. 1998 OIG Report) at 7, 8, App. B-1.) Moreover, in a 1999 press release, Representative Stark reported that “the cost of Ipratropium Bromide to

druggists and doctors has dropped by 50%, but the amount per unit that Medicare pays for this drug has stayed the same.” (*Id.* ¶ 85, Tab 130 (9/1/99 Stark Press Release, “Drug Utilization Soars as Profits Soar”) at 1.) Representative Stark’s press release specifically illustrated the following spreads for Ipratropium: 15% in 1996; 63% in 1997; 96% in 1998; and 108% in 1999. (*Id.*) Unquestionably, VAC’s allegations of Ipratropium AWP inflation were publicly disclosed by 2000. However, even if they were not, there is no doubt that they were disclosed before VAC raised them in its 2002 Complaint. Significantly, in September 2001, the GAO disclosed to Congress, and the public, that Ipratropium had average *discounts of 78%*, equating to “spreads” of **355%**. (*Id.* ¶ 87, Tab 131 (Sept. 2001 GAO Report) at 4, 18.)

Nor can VAC claim that the Government did not have notice of the identity of the manufacturers of Ipratropium because up until approximately 1999, Roxane was one of only three companies selling Ipratropium. In this respect, this case is analogous to *United States ex rel. Harshman v. Alcan Elec. and Eng’g*, 197 F.3d 1014 (9th Cir. 1999), where the public disclosure identified only a small group of potential wrongdoers, involving twenty-two electrical contractors. *Id.* at 1016-17. Prior to filing the FCA action in *Harshman*, the *qui tam* plaintiff lodged a complaint with the District Court alleging that the electrical workers’ union had “conspired with local contractors to deduct certain sums from Union members’ paychecks.” *Id.* at 1016. The court held that the prior complaint was a public disclosure because, from that document, the Government could have easily identified the “local contractors” in question, who belonged to a “narrow class of suspected wrongdoers.” *Id.* at 1019.

The court’s logic in *Harshman* applies with even greater force here because the “class of suspected wrongdoers” consisted of only three companies, one of which was Roxane. Moreover,

Roxane provided information to HCFA on a regular basis in the form of quarterly AMPs for Ipratropium. Thus, there could be no mystery as to whom these allegations referred.

Additional Drugs. VAC cannot credibly claim that there was no public disclosure prior to 2005, when VAC named the eight additional drugs (“Additional Drugs”) at issue. By that time, widespread claims about inflated AWPs and WACs had infiltrated Congressional hearings, courtrooms across the country (including an MDL before this Court in 2003), news media reports, and many additional OIG and other government reports. The Medicare program itself had entirely *abandoned* the AWP system by the end of 2003. (56.1 ¶ 74.) Indeed, this Court has determined that by 2001—*four years* before VAC added the Additional Drugs—there was a “perfect storm” of information that put everyone on notice of so-called “mega spreads.” *In re Pharm. Indus. AWP Litig.*, 491 F. Supp. 2d 20, 41 (D. Mass. 2007).

Furthermore, by 2005, numerous state attorneys general had filed public complaints against Roxane, alleging not only that Roxane had inflated the WACs and AWPs for the Additional Drugs, but that Roxane had “marketed the spread” for those drugs as well.⁷ The State of Texas’ November 2004 complaint is a clear-cut example of the public disclosures in these separate proceedings. Significantly, the Texas complaint identified every one of the Additional Drugs, and all but three of the NDCs at issue in this action. (Ex. A (11/17/04 Texas/VAC Compl., Ex. A).) Allegations with respect to many of the Additional Drugs also echoed in the

⁷ See, e.g., Ex. A (11/17/2004 Texas/VAC Compl.); Ex. B (3/5/2004 Connecticut Compl.); see also Ex. C (7/9/2003 Florida/VAC Compl.); Ex. D (9/25/2003 Massachusetts Compl.); Ex. E (3/10/2004 Pennsylvania Compl.); Ex. F (8/4/2004 City of New York Compl.); Ex. G (11/1/2004 Wisconsin Compl.); Ex. H (11/4/2004 Kentucky Compl.); Ex. I (11/17/2004 Ohio Compl.); Ex. J (1/26/2005 Alabama Compl.); Ex. K (2/7/05 Illinois Compl.).

complaints filed by attorneys general in ten other states.⁸ These complaints plainly constitute public disclosures. *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d at 1339, 1350 (4th Cir. 1994) (“A civil complaint is unquestionably a ‘public disclosure of allegations’”); *Ortho-McNeil*, 538 F. Supp. 2d at 377, 383.

In sum, the foregoing public disclosures exposed both the “X” [that Roxane’s WACs and AWPs were inflated] and the “Y” [that Roxane’s “true” prices were much lower] of the relevant equation, such that “Z” [Roxane’s alleged fraud] could be inferred. Moreover, they contained ample information to alert the Government of potential WAC and AWP inflation by Roxane, and, in fact, the Government did start investigating Roxane’s drugs by 2000. (Ex. L (8/25/00 DOJ Subpoena to Roxane).) Thus, the “critical elements” of VAC’s allegations of WAC and AWP inflation were publicly disclosed before being raised by VAC.

4. *The “Marketing the Spread” Allegations Were Publicly Disclosed Before Being Raised by VAC.*

VAC did not raise its second theory of fraud—that Roxane allegedly “marketed the spread”—until it filed its 2005 Complaint, at the earliest. (Roxane Dkt. No. 2, Ex. 5 ¶ 132.b.) By that time, however, the “critical allegations” underlying the “marketing the spread” theory had been in the public domain for more than a decade. *Barron’s* June 10, 1996 article, “Hooked on Drugs,” is a prime example of the public disclosures. (56.1 ¶¶ 30, 31, Tab 95.) The article reported that “drug providers actually pay wholesale prices that are 60-90% below . . . AWP.” (*Id.* at 15.) But *Barron’s* goes beyond exposing just the “X” and “Y” of the public disclosure equation—it also disclosed the “Z”—that marketing or maintaining spreads may give rise to

⁸ See, e.g., Ex. B (3/5/2004 Connecticut Compl.) pp. 73-75, Table 1-2 (naming six of the eight Additional Drugs); Ex. I (11/17/2004 Ohio Compl.) ¶ 6 (naming five of the eight Additional Drugs).

legal claims. (*Id.* at 16, 18.) In fact, *Barron's* quotes several sources who suggested that the alleged conduct is fraudulent and violates the FCA and the Anti-Kickback Statute:

- an “angry investigator” stated that the “drug makers created false statements so that the doctors could make hundreds of millions of dollars” and that “if OIG doesn’t get them, the Justice Department will” (*id.* at 18);
- “[s]ome investigators view the spreads guaranteed by extreme average wholesale prices as a kind of kickback to doctors, in violation of federal laws” (*id.*); and
- “[o]ne group of infusion-industry veterans is reportedly considering attacking the problem by filing a private suit under the False Claims Act” (*id.*).

Barron's article was by no means the first media report on marketing the spread. Nine years earlier, on July 5, 1987, the Kentucky-based *Lexington Herald-Leader* published a front-page story entitled “Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars.” (*Id.* ¶ 3, Tab 73 at A1.) That article discussed in detail a “sales technique called ‘playing the spread,’” noting that some drug “companies actually advertised that they had a better spread.” (*Id.* at 4-5.) Moreover, the article indicated that “many companies routinely list Average Wholesale Prices and ‘your price’ in their catalogs to show the spread.” (*Id.* at 5.) From these articles alone, it “would not have been difficult for the government to identify [Roxane] as a potential wrongdoer.” *Ortho-McNeil*, 538 F. Supp. 2d at 383 n.10.

Additionally, as indicated above, by 2005, numerous states had brought specific claims against Roxane on these very issues. The State of Connecticut’s March 2004 complaint exemplifies the types of allegations against Roxane that were on file in courts across the nation:

Roxane induced health care providers to purchase its pharmaceuticals, rather than those of competitors, by marketing the wider “spread” on Roxane’s pharmaceuticals to providers, knowing that the larger “spreads” would allow the health care providers to receive more money, and make more of a profit, at the expense of the Connecticut Medical Assistance Program [and Medicare].

(Ex. B (3/5/04 Connecticut Compl.) at p. 32 ¶ 23, p. 42 ¶ 16.) Not only do Connecticut's marketing the spread allegations precede VAC's in time, but they also exceed them in terms of particularity. While Connecticut specifically alleged that *Roxane* marketed the spread, VAC only alleged that the *Defendants* (which numbered in the tens) marketed the spread. (*Cf. id.* at p. 42 ¶ 16 *with* Roxane Dkt. No. 2, Ex. 5 ¶ 132.b.) Connecticut also named several specific drugs for which Roxane purportedly marketed the spread, including Ipratropium. By contrast, VAC failed to name a single one. (*Cf.* Ex. B (3/5/04 Connecticut Compl.) at pp. 78-79, Table 3-2 *with* Roxane Dkt. No. 2, Ex. 5 ¶ 132.b.) Thus, VAC's marketing the spread allegations against Roxane are, at best, just "a rehash of what already had been publicly disclosed." *Wang v. FMC Corp.*, 975 F.2d 1412, 1417 (9th Cir. 1992).

B. VAC's Action Is "Based Upon" The Publicly Disclosed Information.

An action is "based upon" a public disclosure when the "supporting allegations are *similar to or the same as* those that have been publicly disclosed . . . regardless of where the relator obtained his information." *Ortho McNeil*, 538 F. Supp. 2d at 377-79 (emphasis added). A *qui tam* action may be barred, even if it is only partially based upon a public disclosure, and even if the *qui tam* complaint incorporates additional or somewhat different details. *Precision Co.*, 971 F.2d at 552. As demonstrated in detail above, the critical elements of VAC's fraud allegations here are unmistakably similar to the repeated and public disclosures in government reports, news reports, and court-filed documents. Accordingly, VAC's action is "based upon" the public disclosures that revealed the "critical allegations" of fraud.

C. VAC Is Not An "Original Source" Of These Allegations.

There can be no jurisdiction over claims based on publicly disclosed allegations when the relator is not "an original source of the information." § 3730(e)(4)(A). As shown above, this requires both "direct" and "independent" knowledge of the information upon which the

allegations are based. § 3730(e)(4)(B);⁹ *see supra* at 1, 3-4. A relator's knowledge is only direct if it is "marked by the absence of an intervening agency, instrumentality, or influence," *United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 95 (D. Mass. 2001), or "unmediated by anything but [the plaintiff's] own labor," *United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 703 (8th Cir. 1995). Knowledge that is "derivative of the information of others," *United States ex rel. Hafter v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1162 (10th Cir. 1999), or gleaned from a "mere compilation of documents or reports already in the public domain" will not suffice, *Kennard v. Comstock Res., Inc.*, 363 F.3d 1039, 1045 (10th Cir. 2004). In sum, a relator must have first-hand knowledge of the information on which its allegations are based. *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 690 (D.C. Cir. 1997).

The relator must establish that it is an original source as to each claim. *Ortho Mc-Neil*, 538 F. Supp. 2d at 384-85 (adopting a "claim-by-claim" approach). This prevents "jurisdiction in gross just because a relator is an original source with respect to some claim," but not as to others. *Rockwell*, 549 U.S. at 476.

⁹ As a matter of statutory interpretation, § 3730(e)(4)(B) categorically precludes VAC from qualifying as an "original source". While "a person may bring a civil action" under the FCA, § 3730(b)(1) (emphasis added), only "an individual who has direct and independent knowledge" can qualify as an original source, § 3730(e)(4)(B) (emphasis added). Where the term "person" is defined to include an individual or a corporation, as it is for purpose of the FCA, 1 U.S.C. § 1; *see also, e.g.*, *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 782 (2000), the term "individual" does not include corporations, *Lee v. ABC Carpet & Home*, 236 F.R.D. 193, 198 (S.D.N.Y. 2006). Thus, because VAC is a *corporation*, and because the FCA contemplates that only an *individual* can be an original source, VAC, by definition, is not an original source.

1. *VAC's Allegations Are Based Entirely on Second-Hand Data Compiled by and Acquired from Third-Party Sources.*

VAC concedes that its claims are based on nothing more than its review of data compiled by and obtained from third parties. At the outset, one crucial source of information can be ruled-out—and that is Roxane. Never did VAC purchase any drug directly from Roxane, let alone one of the drugs at issue here (Ex. M (7/23/08 Lockwood Dep.) 1081:21-1082:10); nor did it have any direct contracts with Roxane (Ex. N (12/9/08 Jones Dep.) 1205:10-1206:13); nor did Roxane ever advertise the WACs, AWPs, or contract prices of any of its drugs directly to VAC (*id.* at 1206:22-1209:16). In sum, VAC never had *any* interactions with Roxane from which it could have gained direct and independent knowledge. (*Id.* at 1211:1-8.)

Nor did VAC's access to limited pricing information amount to direct and independent knowledge. As an initial matter, VAC has *never* known the pricing of the Novaplus-label Ipratropium product, much less provided it to the Government. (*See* Ex. O (6/19/09 Lockwood Dep.) at 84:16-85:10.) Indeed, aside from the Roxane-label Ipratropium, VAC has never actually purchased *any* of the Roxane drugs at issue from *any* source. (Ex. N (12/9/08 Jones Dep.) at 1201:13-1202:10.) The few units of Ipratropium that VAC did buy were all procured in 2000 or later from wholesalers, distributors, and group purchasing organizations (“GPOs”) at the prices listed by those intermediaries, and not by Roxane. (*Id.* at 1203:22-1204:12.) Moreover, VAC has never actually dispensed Ipratropium to any patient, much less submitted any claims for any of the drugs here. (*Id.* at 1202:11-1203:16.) Indeed, by the mid-1990s, *years* before this lawsuit was filed, VAC had ceased serving patients, and was focused solely on litigation. (*Id.* at 1276:12-1277:6.)

All of VAC's pricing here came from either the pricing compendia (*see* Ex. M (7/23/08 Lockwood Dep.) at 1192:5-1194:3), or third-party wholesalers, distributors, and GPOs (*id.* at

1080:7-1081:12). VAC’s allegations regarding Roxane’s “spreads” are entirely based on its simple cross-comparisons of this data, which were collected and compiled by third parties and widely available to pharmacists across the nation. (*See, e.g.*, Ex. N (12/9/08 Jones Dep.) at 1255:10-1256:15.) For instance, VAC relied heavily on the McKesson Econolink electronic database, which is created and maintained by one the largest wholesalers in the country. (*See* Ex. M (7/23/08 Lockwood Dep.) at 1117:2-20, 1165:16-1166:4.) This database contained thousands of NDCs, including AWPs, list prices, and contract prices, and was accessible to thousands of pharmacists and other providers. (*Id.* at 1141:1-17.) This program made it exceedingly easy to target Roxane drugs; it even calculated the “spread” automatically and displayed it to the provider. (*Id.* at 1112:7-1113:21.) Indeed, VAC’s “discovery” of the alleged spreads here required no more than five minutes of “investigation,” as that is how long it took to generate a printed record of those spreads. (*See* Ex. O (6/19/09 Lockwood Dep.) at 95:20-96:13.)

As opposed to being “marked by the absence of an intermediary,” VAC is at least two-steps removed from the origin of the information on which its allegations are based. To illustrate this point, the WACs and AWPs that VAC claims were inflated were allegedly reported by Roxane (“A”) to the pricing compendia (“B”), which then published those figures to the general public (“C”), including VAC, the Government, and anyone else who subscribed to those publications. Similarly, the “actual prices” at which Roxane allegedly arranged for providers to purchase its drugs were communicated by Roxane (“A”), and filtered through wholesalers, distributors, and GPOs (“B”), before being made available to providers (“C”), such as VAC. Clearly, VAC (“C”), as an outsider to the communications it claims gave rise to the fraud, has no direct knowledge of those communications, and thus can only speculate about their content. It is

well-established, however, that speculation does not amount to direct and independent knowledge. *See United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 163 F.3d 516, 526 (9th Cir. 1999); *Hafter*, 190 F.3d at 1162-63.

Moreover, while VAC claims that it had access—through wholesalers, distributors, and GPOs—to the prices at which Roxane allegedly arranged for *providers* to purchase its drugs, VAC does not claim that it had access to the prices (or the AMPs) at which Roxane sold its drugs to *wholesalers*. Rather, VAC admits that its allegations of WAC inflation are based on “a line of assumptions in general, because [VAC] didn’t have AMP from manufacturers.” (Ex. M (7/28/08 Lockwood Dep.) at 1169:4-17.) In fact, VAC’s allegations that Roxane’s WACs were inflated are based on guesstimates as to wholesale costs, given the particular list price offered by the wholesaler to providers. (*Id.* at 1169:4-1171:8). To the extent that VAC could access the list price of a certain drug—for example, through the Econolink database—VAC would just assume that list price was within five percent of the wholesaler’s acquisition cost. (*Id.* at 1107:12-1108:13.) Like its AWP-based allegations, VAC’s WAC-based allegations are founded not on direct knowledge, but on speculation and conjecture. *See Aflatooni*, 163 F.3d at 526; *see also Hafter*, 190 F.3d at 1162-63.¹⁰

Given that VAC’s WAC and AWP inflation allegations depend on data furnished by third-party sources, VAC’s knowledge is not “direct and independent.” *O’Keefe*, 131 F. Supp. 2d at 96 (knowledge gained through the analysis of existing data was not direct). Neither can VAC’s “assumptions” based on its “underst[anding of] the way the market worked” (Ex. N

¹⁰ Similarly, the WAC figures that VAC claimed were inflated in its 2000 Complaint were obtained not from Roxane, but from the State of Texas. To the extent that VAC (“C”) obtained from state plaintiffs in other AWP actions (“B”), certain WAC figures reported by Roxane (“A”), (Ex. M (7/23/08 Lockwood Dep.) at 1136:11-1138:11), such knowledge is certainly not direct.

(12/9/08 Jones Dep.) at 1236:2-13) convert the nature of its knowledge, indirect as it is, into knowledge that is direct and independent. *See Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002) (analysis of data in the public domain did not give rise to direct and independent knowledge, regardless of the time and expertise devoted to bring the alleged fraud to light).

2. *VAC Does Not Have Direct and Independent Knowledge of “Marketing the Spread” Allegations.*

With respect to the marketing the spread allegations, VAC lacks knowledge altogether. At the heart of the marketing the spread theory against Roxane are allegations that Roxane “manipulated and controlled” the spread for its drugs, “trained its sales force” on the “importance of the ‘spread,’” and “actively marketed the spread.” (Dkt. No. 96 ¶¶ 64-66.) However, VAC admittedly never had *any* communications with Roxane at all. (Ex. M (7/23/08 Lockwood Dep.) at 1181:7-1182:3.) VAC concedes—as it must—that it knows nothing about how Roxane trained its sales force or how it internally decided to price or market its drugs. (*Id.* at 1184:18-1185:10, 1192:5-1194:3; Ex. N (12/9/08 Jones Dep.) at 1224:8-1227:6.) Moreover, VAC specifically admits that Roxane did not market the spread to VAC, and that it is not aware of any advertisements by Roxane to other providers. (Ex. M (7/23/08 Lockwood Dep.) at 1185:11-1186:14, 1156:10-18, 1158:8-15.) For instance, when asked about the basis for the allegations that Roxane marketed the spread, VAC representative John Lockwood testified as follows:

- Q. You are not contending that any Roxane salesperson or employee ever marketed a spread on any of Roxane’s drugs to Ven-A-Care?
- A. No, I’m not aware of any Roxane salesperson coming to Ven-A-Care and knocking on the door or calling us directly, who is a Roxane employee and marketing to us, I’m not aware of that, no.

(*Id.* at 1186:6-14 (objections omitted).)

Q. And you don't recall any advertisements provided directly to physicians or pharmacists by any Roxane drug company representatives?

A. Um, no, I don't recall any by representatives from -- from Roxane, the company; as I said, it may -- sometimes there is some marketing material from the GPOs, I would have to go look.

(*Id.* at 1158:8-15.) In light of testimony such as this, VAC cannot be an original source of the marketing the spread allegations.

CONCLUSION

For all the foregoing reasons, the Court lacks jurisdiction over VAC's claims against Roxane and should dismiss VAC's action with prejudice.

Dated: June 26, 2009

Respectfully submitted,

/s/ John W. Reale
Helen E. Witt, P.C.
Anne M. Sidrys, P.C.
Eric T. Gortner
John W. Reale
KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, IL 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200

*Counsel for Defendants
Boehringer Ingelheim Corp.,
Boehringer Ingelheim Pharmaceuticals, Inc.,
Boehringer Ingelheim Roxane, Inc., and
Roxane Laboratories, Inc.*

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on June 26, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/

John W. Reale

John W. Reale